FDA 510K Summary of Safety and Effectiveness for Clareblend LED Probes

OCT 01 2008

K073022

1. General Information

Submitter:

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Contact Person:

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Elgin, IL 60123
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Summary Preparation Date: October 26, 2007

2. Names

Device Name: Clareblend LED Probe
Model # 7201-415, 7204-631, 7205-830

Classification Name: Laser instrument, surgical, powered device; GEX, ILY
FDA Class II category

Although this device is not a laser, the specifications developer feels this is the closest applicable classification name.

3. Predicate Device

Clareblend LED Probes Models 7201-415, 7204-631, 7205-830 are substantially equivalent to Omnilux Blue (K030883), Omnilux Revive (K030426), Omnilux Plus (K043317)

4. Device Description

The Clareblend Probes are hand held devices that utilizes Light Emitting Diodes to provide LED light to the body. The hand hold device contains the power supply. The probe will be simply activated by an alternate action ON/OFF pushbutton switch which is located on the top of the probe. The probe when activated applies full power (100% duty cycle). The OFF button is provided for the user to immediately remove all power to the probes. The probe housing is 100% machined aluminum and has a recessed clear lexan window. The device delivers the light to the skin as it moves over the skin. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength of Red is 631 +/- 4nm, IR is 830 +/- 5nm and Blue is 415 +/- 5nm.

5. Indications for Use:

Clareblend Probe (Red-631) is generally indicated for the treatment of superficial, benign vascular and pigmented lesions
Clareblend Probe (Blue-415) is generally indicated for the treatment of dermatological conditions and specially indicated for the treatment of mild to moderate inflammatory acne vulgaris.
Clareblend Probe (IR-830) is generally indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

6. Comparison of Technological Differences: K073022

The intended use and technological characteristics of the Clareblend Probes are virtually identical to the intended use and technological characteristics of the listed equivalent devices. Any differences between the Clareblend Probes and the equivalent devices have no significant influence on safety or effectiveness of the Clareblend Probes product.

7. Conclusions

Based upon an analysis of the overall performance characteristics for the Clareblend Probes, Clareblend, Inc. believes that no significant differences exist between this system and the predicate systems quoted, therefore, the Clareblend Probes do not impose any new safety or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2008

Clareblend, Inc.
% Aesthetica-Tech
Ms. Jill Creasy
Medical Device Consultant
675 Pine Street
Elgin, Illinois 60123

Re: K073022
Trade/Device Name: Clareblend LED Probes Model # 7201-415, 7204-631, 7205-830
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX, ILY
Dated: September 15, 2008
Received: September 18, 2008

Dear Ms. Creasy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

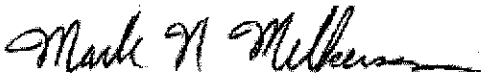
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 073022

Device Name: Clareblend LED Probes
Model # 7201-415, 7204-631, 7205-830

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The Clareblend Probes are intended to provide light to the body.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073022